

PCT

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

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(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 13189-5PCT	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/PEA/416)	
International application No. PCT/CA 03/01690	International filing date (day/month/year) 31.10.2003	Priority date (day/month/year) 01.11.2002
International Patent Classification (IPC) or both national classification and IPC C12Q1/18		
Applicant MIRADOR DNA DESIGN INC. et al.		



1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 5 sheets, including this cover sheet.

☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 2 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the opinion
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 01.06.2004	Date of completion of this report 22.11.2004
Name and mailing address of the international preliminary examining authority:  European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Authorized Officer Scott, J Telephone No. +31 70 340-2206 

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. **PCT/CA 03/01690**

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

Description, Pages

1-20 as originally filed

Claims, Numbers

1-11 received on 26.10.2004 with letter of 26.10.2004

Drawings, Sheets

1/8-8/8 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

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5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	1-11
	No: Claims	
Inventive step (IS)	Yes: Claims	1-11
	No: Claims	
Industrial applicability (IA)	Yes: Claims	1-11
	No: Claims	

2. Citations and explanations

see separate sheet

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following documents :

D1 : EP - A - 0 354 027
D2 : EP - A - 0 950 403
D3 : US - A - 5 317 042
D4 : US - A - 4 596 770
D5 : WO - A - 98 / 50566

D1 discloses a biodegradable, non-toxic, non-hazardous solvent composition which comprises according to claim 8, up to 50% by weight of N-Methylpyrrolidone, and at least 50% of a mixture containing para-methadienes and terpene hydrocarbons (this latter mixture appears to fall within the general definition of "essential oil" - more particularly "pine terpenoids". The subject-matter of claim 1 of the present application is novel, over D1, in that it is suitable for chromogenic substrates as opposed to cleaning or de-greasing as is the case for D1.

D2 details an emulsion for in-situ delivery systems for sustained delivery of a biologically active agent. More specifically, example 1 describes polymer solution with propylene carbonate present, and example 2 details the same with N-Methylpyrrolidone. Example 3 uses sesame oil, peanut oil, or castor oil. The subject-matter of claim 1 of the present application is novel, over D2, in that the above-mentioned oils would not be said to fall within the scope of the term "essential oil"

D3 discloses an aqueous microemulsion which amongst others contains N-methylpyrrolidone. The subject-matter of claim 1 of the present application is novel, over D3, in that it is suitable for chromogenic substrates as opposed to use as an insecticide as is the case for D3.

D4 uses aqueous N-Methyl pyrrolidone as a solvent for the substrate containing tetraalkyl benzidine chromogen and a peroxide in determining peroxidase enzyme activity, and this use of NMP provides increased stability of the substrate solution. The subject-matter of claim 1 of the present application is novel, over D4, in that there is no mention of the "essential oil" being used simultaneously with the NMP.

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EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/CA 03/01690

Thus the present application meets the criteria of Article 33(1) PCT, because the subject-matter of claims 1-11 is new in the sense of Article 33(2) PCT.

The document D5 is regarded as being the closest prior art and discloses D5 discloses a method for screening for indicia of the lac operon using a chromogenic substrate cleavable by B-galactosidase.

The subject-matter of claim 1 therefore differs D5 in that : there is no mention of the stabilizing amount of the solubilizing agent or the essential oil.

The effect of this difference is that the solubilizing agent used is now non-toxic, and provides extended stability to the chromogenic substrate solution.

The problem to be solved by the present invention may therefore be regarded as the provision of an improved solvent for detecting the presence of the lacZ gene.

The solution proposed in claim 1 of the present application is considered as involving an inventive step since the skilled person could not expect the combination of NMP, DMPU or PC with an essential oil would even work, let alone that it would result in the improvements listed above.

Thus the application meets the criteria of Article 33(1) PCT, because the subject-matter of claims 1-11 not involves an inventive step in the sense of Article 33(3) PCT.